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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,904	04/16/2004	Mitchell Shirvan	29340U	2223

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EXAMINER	
HUI SAN MING R	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
04/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,904	SHIRVAN ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,47 and 93-101* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,47 and 93-101* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed January 8, 2009 has been entered.

Claims 1-10, 47, and 93-101 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10, 47, and 93-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bialer et al. (US Patent 5,585,358, reference of record) and IE 0052415 ('415) in view of Hansen (Southern Medical Journal, 1999;92(7):642-649), McQuay et al. (BMJ, 1995;311:1047-1052), Shank et al. (US Patent 5,760,007), Carrazana et al. (US Patent 6,319,903), Magnus (Epilepsia, 1999;40(Suppl 6):S66-S72), Zakrzewska et al. (Pain 1997;73(2):233-230), and Merck Manual (16th ed., 1992, page 1412), references of record in the parent application.

Bialer et al. teaches the elected compound, N-(2-n-propylpentanoyl) glycinamide, is useful as anticonvulsant for treating epilepsy and other neurological disorders (see the abstract, and col. 7, line 23-44, Example 1; col. 13, line 4 – col.17, line 34). Bialer et al. teaches the effective dose in a composition for N-(2-n-propylpentanoyl) glycinamide as 10 to about 500mg (col. 3, line 59-61). Bialer et al. also teaches the ED_{50} dosage of N-(2-n-propylpentanoyl) glycinamide for antiepileptic activities as 73mg/kg (about 5000mg in an 70kg adult) (See col. 13, line 39). Bialer et al. also teaches N-(2-n-propylpentanoyl) glycinamide can be administered through oral, intravenous, intraperitoneal, intramuscular, and topical (See col. 7, line 10-14). Bialer et al. also teaches those skilled in the art would be able to determine the precise effective amount and routes of administration of the herein compound to be administered (See col. 6, line 49-59).

'415 teaches the compounds which encompassed by the compounds recite in claims 4-5 (See page 2, compounds of Formula (I), when R1 or R2 is alkyl phenyl or araalkyl). '415 also teaches the compounds have antiepileptic effect (See page 10 and 11).

The references do not expressly teach N-(2-n-propylpentanoyl) glycinamide and the compounds of '415 to be useful as treating or preventing acute, chronic, neuropathic pain, or cancer pain. The references do not expressly teach the dosage of N-(2-n-propylpentanoyl) glycinamide or that of the compounds of '415as 6000mg or 3000mg. The references do not expressly teach the route of administration as intranasal, sublingual, inhalation, buccal, intravaginal, and pulmonary. The references do not

expressly teach the dosing frequency of N-(2-n-propylpentanoyl) glycinamide or the compounds of '415 as periodic six times daily.

Hansen teaches various antiepileptic agents are useful in treating both acute and chronic pain (See page 642, col. 2, second paragraph, page 646, col. 2, fourth paragraph to page 647, whole page).

McQuay et al. teaches the effectiveness of various anticonvulsants such as carbamazeoine, phenytoin, Valproate sodium are effective in treating neuropathic pain such as trigeminal neuralgia, cancer pain, rheumatoid arthritis and migraine prophylaxis in various degree (See the abstract, Tables 1-4, also Section Trigeminal neuralgia and Migraine prophylaxis).

Shank et al. teaches topiramate, an anticonvulsant, is useful in treating neuropathic pain (See claim 2).

Carrazana et al. teaches topiramate, an anticonvulsant, is useful in treating cluster headaches (See claims 1-15).

Magnus teaches gapapentin, an anticonvulsant, is useful in treating neuropathic pain and useful in migraine prophylaxis (See Summary, also page S66 to S68, first col. Second paragraph; also page S71, Table 5).

Zakrzewska et al. teaches lamotrigine, an anticonvulsant, is useful in treating trigeminal neuralgia, a neuropathic pain. (See the abstract).

Merck Manual teaches that peripheral neuropathy pain is associated with tumor infiltration, which is a neuropathic pain (See page 1412).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ N-(2-n-propylpentanoyl) glycinamide or the compounds of '415, in the herein claimed dosage and dosing regimen, in a method of treating and prophylaxis pain. It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer N-(2-n-propylpentanoyl) glycinamide or the compounds of '415 in the herein claimed routes of administration.

One of ordinary skill in the art would have been motivated to employ N-(2-n-propylpentanoyl) glycinamide or the compounds of '415, in the herein claimed dosage and dosing regimen, in a method of treating and prophylaxis pain. Based on the cited prior art, antiepileptic compounds with vastly different structure and mechanism of actions are useful for treating and preventing neuropathic pain, migraine headache and cluster headache. The only common property of these antiepileptic compounds is that they are all useful as anticonvulsant. Therefore, employing any known anticonvulsant, including the N-(2-n-propylpentanoyl) glycinamide, or the compounds of '415 would have been reasonably expected to be useful to treat or prevent neuropathic pain such as peripheral neuropathic pain associated with tumor infiltration, migraine headache and cluster headache. Furthermore, the optimization of result effect parameters (e.g., dosage range, dosing regimens) is obvious as being within the skill of the artisan, based on the teachings of Bialer et al. (See col. 6, line 49-59).

One of ordinary skill in the art would have been motivated to administer N-(2-n-propylpentanoyl) glycinamide or the compounds of '415in the herein claimed routes of administration because one of ordinary skill in the art would be charge to possess all the

conventional method of administering a therapeutic compound. Selecting the herein claimed routes of administration over the obvious alternatives would be considered obvious as being within the purview of a skilled artisan, absent evidence to the contrary.

Response to Arguments

Applicant's arguments filed January 8, 2009 averring the cited prior art's failure to provide suggestion and motivation to employ the VPA derivatives in a method of treating pain because of the teachings of the references in various medical journal have been fully considered but they are not persuasive. The examiner notes that the applicant has not provided the references cited in the response and therefore, the examiner would not be able to evaluate the references whether it would obviate the rejection under 35 USC 103(a). Furthermore, the examiner notes that some of the references are published after the effective filing date of the instant application. Therefore, those references cannot be the probative evidence for non-obviousness.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon - Fri from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

San-ming Hui
Primary Examiner
Art Unit 1617

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